

### **Remarks**

Claims 1, 19, and 21-22 are amended herein. The amendments to claims 19 and 21-22 were made for clarification to correct obvious editorial errors.

Claim 23 was labeled “Original” in the last response. That label was incorrect, as the word “derivative” was added to the claim.

#### *35 U.S.C. § 102*

Claims 1-15 and 19-27 were rejected as being anticipated by Guy (U.S. Patent No. 5,576,311). Anticipation requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP 2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

#### **Claims 1-15 and 26**

Guy does not mention “delivering a therapeutically effective amount of a therapeutically active agent to a structure or combination of structures of the eye which include the vitreous humor and structures posterior to the vitreous.” Thus, Guy does not anticipate the claims.

The Office Action asserts that the compositions of Guy are used “for the treatment of ophthalmic disorders.” However, this is not “delivering a therapeutically effective amount of a therapeutically active agent to a structure or combination of structures of the eye which include the vitreous humor and structures posterior to the vitreous.” There are many ophthalmic disorders that may be treated without carrying out the claimed method. Thus, Guy does not anticipate the claims.

#### **Claims 19, 21, and 22**

Guy teaches “aqueous suspension of drugs suitable for therapeutic administration without requiring solubilization or complexation of those drugs.” (Abstract.) The claims are drawn toward a product “comprising a solution.” Thus, since a solution is not a suspension, the claims are not anticipated.

Guy also does not teach dispensing the composition from “a package which indicates that said product is useful for treatment of a disease or condition affecting the back of the eye.” Thus, the claims are not anticipated.

#### **Claims 20, 23-25, and 27**

Guy does not teach that “the amount of the therapeutically active agent or salt or prodrug thereof and the amount of the cyclodextrin are effective to deliver a therapeutically effective amount of said therapeutically active agent to a structure or combination of structures of the eye which include the vitreous humor and structures posterior to the vitreous.” Thus, Guy does not anticipate the claim.

The Office appears to be relying upon the notion that the claimed method “may result” from the disclosure of Guy. However, this is improper. “Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). Thus, the Office has not shown that the claims are anticipated, and the rejection should be withdrawn.

#### *35 U.S.C. § 103*

No *prima facie* case of obviousness has been made. MPEP 2143 states that “the prior art reference (or references when combined) must teach or suggest all the claim limitations.”

#### **Claims 1-15 and 26**

The Office Action has not explained how the cited references, alone or in combination, teach or suggest “delivering a therapeutically effective amount of a therapeutically active agent to a structure or combination of structures of the eye which include the vitreous humor and structures posterior to the vitreous.” Thus, a *prima facie* case of obviousness has not been made.

**Claims 19, 21, and 22**

The Office Action has not explained how the cited references, alone or in combination, teach or suggest dispensing the composition from “a package which indicates that said product is useful for treatment of a disease or condition affecting the back of the eye.” Thus, a *prima facie* case of obviousness has not been made.

**Claims 20, 23-25, and 27**

The Office Action has not explained how the cited references teach or suggest that “the amount of the therapeutically active agent or salt or prodrug thereof and the amount of the cyclodextrin are effective to deliver a therapeutically effective amount of said therapeutically active agent to a structure or combination of structures of the eye which include the vitreous humor and structures posterior to the vitreous.” Thus, a *prima facie* case of obviousness has not been made.

In light of the amendments and the arguments made herein. Applicants believe that the claims are patentable as they now stand, and respectfully request that Examiner remove the rejections and allow the application to pass to issue.

Please use Deposit Account 01-0885 for extension of time fees or any other fees or credits relating to this response.

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Respectfully submitted,

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